UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GAYLE MILES,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION H-19-4319
	§	
BOSTON SCIENTIFIC CORPORATION,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Pending before the court is defendant Boston Scientific Corporation's ("Boston Scientific") motion to dismiss. Dkt. 15. In response, plaintiff Gayle Miles ("Miles") argues Boston Scientific's motion should be denied, or alternatively requests leave to amend her complaint. Dkt. 20. Boston Scientific replied. Dkt. 25. After reviewing the motion, response, reply, and applicable law, Boston Scientific's motion (Dkt. 15) should be **GRANTED** in part and **DENIED** in part.

I. BACKGROUND

This case involves fraud and product liability claims against Boston Scientific. On April 24, 2006, Miles was implanted with Advantage Fit, a pelvic mesh product manufactured by Boston Scientific. Dkt. 1 at 12. Advantage Fit was intended to treat her for stress urinary incontinence ("SUI"), a use for which Boston Scientific markets Advantage Fit, and Miles claims that her physician implanted her Advantage Fit properly and appropriately. *Id.* Miles alleges Boston Scientific failed to properly disclose inherent risks associated with Advantage Fit, which led to her injuries. *Id.*

The Advantage Fit is a Class II medical device for which Boston Scientific obtained FDA marketing clearance to correct pelvic organ prolapse (POP) and SUI. *Id.* at 2-3. Since Advantage

Fit's market entry, industry and regulatory officials have issued several communications related to the product's efficacy in treating POP:

> 1) a 2011 FDA Safety Communication identifying serious complications associated with the surgical mesh for transvaginal repair of POP as not rare, including mesh contraction as a previously unidentified risk associated with vaginal shortening, tightening, and pain;
>
> 2) a 2011 FDA white paper expressing "serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of [POP]"; and
>
> 3) a 2011 Joint Committee Opinion released by the American College of Obstetricians and Gynecologists and the American Urogynecologic Society identifying physical and mechanical changes to pelvic mesh products inside the body as a serious complication of implantation.

Id. at 3-5.

Also in 2011, the FDA acknowledged that the literature on SUI repair with mesh "indicates that serious complications can occur . . . [and] a case can be made for additional . . . studies to better address the risk/benefit of all mesh products used for SUI." *Id.* at 5. In January 2012, the FDA subsequently issued a Section 522 order to manufacturers of pelvic mesh products used to treat SUI, which required them to begin monitoring their patients' outcomes after implantation in order to collect useful data on potential safety risks (the "Section 522 Order"). *Id.*

Miles claims Boston Scientific knew the risks associated with POP repair are the same as SUI repair, and it has not adequately studied the extent of the risks associated with Advantage Fit. *Id.* She further alleges Boston Scientific knew or should have known the risk of serious injuries from use of Advantage Fit, but continued to market it to physicians and patients, including herself, without adequate warnings. *Id.* at 5-6, 8. Had Boston Scientific properly disclosed the risks associated with the Advantage Fit, Miles claims she would not have used it. *Id.* at 12.

Miles identifies a multitude of Advantage Fit's defects, including:

1) the use of polypropylene and the immune reactions that result from such material, causing adverse reactions and injuries;

2) the design of Advantage Fit to be inserted into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

3) biomechanical issues with the design of Advantage Fit, including, but not limited to its propensity to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

4) the use and design of arms and anchors, which, when placed in the patient, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

5) the propensity for "creep" or to gradually elongate and deform when subject to prolonged tension inside the body;

6) the inelasticity of Advantage Fit, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

7) the propensity of Advantage Fit for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time; and

8) the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

Id. at 13.

She separately identifies the risks of which Boston Scientific failed to adequately warn her or her physician:

1) Advantage Fit's propensities to contract, retract, and/or shrink inside the body;

2) Advantage Fit's propensities for degradation, fragmentation and/or creep;

3) Advantage Fit's inelasticity preventing proper mating with the pelvic floor and vaginal region;

4) the frequency and manner of mesh erosion or extrusion;

5) the risk of chronic inflammation resulting from Advantage Fit;

6) the risk of chronic infections resulting from Advantage Fit;

7) the risk of permanent vaginal or pelvic scarring as a result of Advantage Fit;

8) the risk of recurrent, intractable pelvic pain and other pain resulting from Advantage Fit;

9) the need for corrective or revision surgery to adjust or remove Advantage Fit;

10) the severity of complications that could arise as a result of implantation of Advantage Fit;

11) the hazards associated with Advantage Fit;

12) Advantage Fit is no more effective than feasible available alternatives;

13) treatment of pelvic organ prolapse and stress urinary incontinence with Advantage Fit exposes patients to greater risk than feasible available alternatives;

14) treatment of pelvic organ prolapse and stress urinary incontinence with Advantage Fit makes future surgical repair more difficult than feasible available alternatives;

15) use of Advantage Fit puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

16) removal of Advantage Fit due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

17) complete removal of Advantage Fit may not be possible and may not result in complete resolution of the complications, including pain.

Id. at 8.

Miles filed suit against Boston Scientific on November 1, 2019. Dkt. 1. On December 23, 2019, Boston Scientific filed a motion to dismiss Miles's claims for failure to state a claim. Dkt. 15. Miles responded on February 28, 2020. Dkt. 20. Boston Scientific replied on March 13, 2020. Dkt. 25.

II. LEGAL STANDARD

"Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). In considering a Rule 12(b)(6) motion to dismiss a complaint, courts generally must accept the factual allegations contained in the complaint as true. *Kaiser Aluminum & Chem. Sales, Inc. v. Avondale Shipyards, Inc.*, 677 F.2d 1045, 1050 (5th Cir. 1982). The court does not look beyond the face of the pleadings in determining whether the plaintiff has stated a claim under Rule 12(b)(6). *Spivey v. Robertson*, 197 F.3d 772, 774 (5th Cir. 1999). "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, [but] a plaintiff's obligation to provide the 'grounds' of [her] 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. The "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Id.* The supporting facts must be plausible - enough to raise a reasonable expectation that discovery will reveal further supporting evidence. *Id.* at 556.

Although defenses, such as statute of limitations, are generally not an appropriate basis for a Rule 12(b)(6) motion, "certain affirmative defenses that clearly appear on the face of the plaintiff's complaint may properly be asserted in a Rule 12(b)(6) motion." *Songbyrd, Inc. v. Bearsville Records, Inc.*, 104 F.3d 773, 776 n.3 (5th Cir. 1997) (citing *Kansa Reinsurance Co. v. Cong. Mortgage Corp. of Texas*, 20 F.3d 1362, 1366 (5th Cir. 1994)). "[W]here the issue of limitations requires a determination of when a claim begins to accrue, the complaint should be dismissed only if the evidence is so clear that there is no genuine factual issue and the determination can be made as a matter of law." *Askanase v. Fatjo*, 828 F. Supp. 465, 469 (S.D. Tex. 1993) (Crone, J.).

III. ANALYSIS

A. Statute of Limitations

Boston Scientific argues Miles's cause of action is barred by the two-year statute of limitations because it accrued in 2012 but her complaint was not filed until 2019, seven years later. Dkt. 16 at 2-3. Miles asserts the discovery rule as an exception to the statute of limitations and argues that the nature of her injuries and their relationship to Advantage Fit was not and could not have reasonably been discovered until a date within the statute of limitations. Dkt. 1 at 24.

Under Texas law, product liability suits are considered personal injury claims, which must be filed within two years of a cause of action's accrual—generally when a wrongful act causes an injury. TEX. CIV. PRAC. & REM. CODE § 16.003(a); *see also Childs v. Haussecker*, 974 S.W.2d 31, 36 (Tex. 1998). However, courts may invoke the discovery rule and defer accrual of a cause of action until the plaintiff knew, or through the exercise of reasonable care and diligence should have known, the nature of her injury. *Computer Assocs. Int'l, Inc. v. Altai, Inc.*, 918 S.W.2d 453, 455 (Tex. 1996)). Texas courts apply the discovery rule to injuries resulting from an implanted device. *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467 (5th Cir. 1999); *see also Brandau v. Howmedica Osteonics Corp.*, 439 Fed. App'x. 317, 322 (5th Cir. 2011) (applying the discovery rule to a product liability claim based on an injury from a knee replacement implant).

Under this rule, discovery does not mean "actual knowledge of the particulars of a cause of action," but instead occurs "when a plaintiff has knowledge of such facts as would cause a reasonably prudent person to make an inquiry that would lead to discovery of the cause of action." *Vaught v. Showa Denko K.K.*, 107 F.3d 1137, 1140-42 (5th Cir. 1997). A plaintiff who has acquired knowledge of such facts must proceed with a reasonable and diligent investigation and is charged

with the knowledge of all facts such an investigation would have disclosed. *Jensen v. Snellings*, 841 F.2d 600, 607 (5th Cir. 1988).

Evidence of extensive media coverage can qualify as "sufficient facts" to cause a reasonably prudent person to make further inquiry. *Winters v. Diamond Shamrock Chem. Co.*, 149 F.3d 387, 404 (5th Cir. 1998). In *Winters*, the court found that "numerous newspaper articles and excerpts from television and radio reports . . . that concern[ed] Agent Orange and its alleged deleterious effects on veterans who were exposed to it in Vietnam" were sufficient facts to invoke the plaintiff's duty to inquire further. *Id.* In particular, the fact that almost all of the reports state that the chemical "is alleged to have caused various illness[es], including cancer" put within the plaintiff's grasp such facts as would cause a reasonably prudent person to make an inquiry that would lead to discovery of the cause of action. *Id.* at 403. However, plaintiffs have no duty to inquire further simply because some media coverage or press materials link the plaintiffs' injuries to a dangerous product. Only extensive media coverage, like that in *Winters*, is sufficient to precipitate a duty to inquire further. *Id.*; see also *Eberhardt v. Merck & Co.*, 106 Fed. App'x. 277, 279 (5th Cir. 2004) (finding articles showing a potential connection between the plaintiff's injury and a prescription drug were insufficient to put him on notice to inquire further).

Miles alleges her injuries occurred on April 24, 2006, the date her Advantage Fit was implanted. Dkt. 1 at 12. Miles filed her complaint on November 1, 2019, more than 13 years after implantation. Dkt. 1. Both parties agree the discovery rule applies to her claims, and indeed because her alleged injuries stem from an implanted device, Miles is entitled to the discovery rule. *See Porterfield*, 183 F.3d at 467. Therefore, the question becomes when Miles had knowledge of such facts as would cause a reasonably prudent person to make an inquiry that would lead to discovery of the cause of action. *See Vaught*, 107 F.3d at 1140.

Boston Scientific argues Miles's cause of action accrued in 2012, the year in which she knew or had reason to know of her injuries based on publicly available information Miles cited in her complaint. Dkt. 16 at 5-6; Dkt. 1 at 3, 5. Miles claims that the nature of her injuries and their relationship to Advantage Fit was not discovered and could not have been discovered through reasonable care and due diligence, until some time after November 1, 2017. Dkt. 1 at 24 (stating Miles could not have discovered her injury until "a date within the applicable statute of limitations for filing [her] claim").

Boston Scientific's statute of limitations defense can only be an appropriate basis for dismissal if it is clear on the face of Miles's complaint that she knew such facts as would cause a reasonably prudent person to make an inquiry that would lead to the discovery of her cause of action. *See Songbyrd, Inc.*, 104 F.3d at 776 n.3; *see also Vaught*, 107 F.3d at 1140. In her complaint, Miles points to FDA communications and an industry group's opinion to allege Boston Scientific knew or should have known the nature of the risks of Advantage Fit. Dkt. 1 at 3, 5. However, these are not newspaper or online articles an average reader would encounter, nor examples of extensive media coverage like in *Winters*.

Because the facts in the complaint here do not rise to the level of *Winters*, it is not clear on the face of Miles's complaint that the statute of limitations bars her claims. Further factual development is required to determine when the statute of limitations began on Miles's claims. Thus, Boston Scientific's statute of limitations defense is not an appropriate basis for dismissal.

B. Failure to State a Claim under Rule 12(b)(6)

Next, Boston Scientific asserts Miles's claims for manufacturing defect and failure to warn should be dismissed because Miles does not plead sufficient facts to state a plausible claim for which relief can be granted. Dkt. 16 at 7-12.

1. *Manufacturing Defect*

Miles alleges a product liability claim against Boston Scientific for defective manufacture of her Advantage Fit. Dkt. 1. To succeed on a manufacturing defect claim, Texas law requires a plaintiff to prove a product deviates "from the specifications or planned output in a manner that renders it unreasonably dangerous." *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 600 (Tex. 2004). A plaintiff must show that the product was defective "when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries." *Id.*

Boston Scientific contends Miles fails to allege how the Advantage Fit deviated from its specifications or planned output of other units at the time it left the manufacturer in a way that rendered it unreasonably dangerous. Dkt. 16 at 8. It also claims Miles fails to allege how Advantage Fit's defective manufacture caused her injuries. *Id.* In response, Miles points to "over eight specific defects present in [her] Advantage Fit" as well as several general allegations that Advantage Fit deviated from Boston Scientific's own design which caused her injuries. Dkt. 20 at 7-8.

A manufacturing defect claim is impermissibly conclusory and vague when the complaint does not specify 1) the manufacturing defect; 2) a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury; and 3) how the manufacturing process failed or how the manufacturing process deviated from the FDA manufacturing process. *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). This standard is met when a plaintiff pleads that "the FDA warned [the defendant] of [risks] in the manufacture of its [product], that the [product], including the [product] implanted into [the plaintiff], were ultimately recalled . . ., and that [the product] caused the type of injury that is consistent with [the identified risk]." *Bass v. Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012); *see also Riddell v. Howmedica Osteonics Corp.*, No. 3:14-cv-705, 2015 WL 5167039, at *16 (S.D. Miss. Sept. 3, 2015)

(denying a motion to dismiss when (i) the plaintiff pled that she received the product; (ii) the defendant manufactured the product; (iii) the FDA previously detected problems that led to the same conditions the plaintiff allegedly suffered after receiving the product; and (iv) the defendant violated specific FDA regulations causing the risk).

However, general allegations that pelvic mesh products are "susceptible to deformation and degradation once placed inside the body" are insufficient to state a claim for a manufacturing defect as they do not "allege[] in any detail [the product]'s intended designs or specifications, how [its] manufacture deviated from those designs or specifications, or how such a deviation caused the alleged susceptibility once within the body." *Fearrington v. Boston Sci. Corp.*, 410 F. Supp. 3d 794, 803 (S.D. Tex. 2019) (Lake, J.).

Miles alleges several defects of Advantage Fit, including its use of polypropoylene material, arms, and anchors, and its propensity to contract or shrink, elongate and deform, and degrade and fragment inside the body. *Id.* at 13-14. Further, Miles generally states in her complaint that the Advantage Fit "implanted in [her] was not reasonably safe for its intended uses and was defective . . . with respect to [its] manufacture, in that it deviated materially from Defendant's design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm." *Id.* at 16. Miles alleges that "as a direct and proximate result of Advantage Fit's aforementioned defects, . . . [she] has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and/or corrective surgery and hospitalization, has suffered financial or economic loss . . ., and other damages." *Id.*

While Miles specifies the alleged manufacturing defect, she does not plead with sufficiency the causal connection between the failure of the specific manufacturing process and the specific defect in the process which caused her injury. *See Funk*, 631 F.3d at 782. Nor does she plead how

the manufacturing process failed or deviated from the FDA-approved manufacturing process. *Id.* Miles references several FDA communications identifying risks associated with using pelvic mesh products to treat POP, however these documents do not address risks of Advantage Fit in treating her condition, SUI. Dkt. 1 at 3, 5. Miles also references the Section 522 Order, but this order only mandated the monitoring of SUI patient outcomes post-implantation. *Id.* at 5. The Section 522 Order alone does not demonstrate that Boston Scientific violated specific FDA regulations causing the risk. *See Riddell*, 2015 WL 5167039, at *16. Finally, Miles never pleads that Advantage Fit was recalled. *See Bass*, 669 F.3d at 510.

Absent details alleging how the manufacturing process failed or deviated from the FDA-approved manufacturing process, Miles has not sufficiently pled a necessary element of her manufacturing defect claim. *See Fearrington*, 410 F. Supp. 3d at 803. Therefore, her complaint does not meet federal pleading standards for stating a plausible claim for which relief can be granted.

2. *Failure to Warn*

Miles also alleges Boston Scientific failed to warn her and her physicians of the risks related to Advantage Fit. Dkt. 1. Texas law requires a plaintiff alleging a failure to warn claim to prove that "1) a risk of harm is inherent in the product or which may arise from the intended or reasonably anticipated use of the product; 2) the product suppliers actually knew or should have reasonably foreseen the risk of harm at the time the product was marketed; 3) the product contains a marketing defect; 4) the absence of a warning renders the product unreasonably dangerous to the ultimate user or consumer of the product; and 5) the failure to warn must constitute a causative nexus in the product user's injury." *Wright v. Ford Motor Co.*, 508 F.3d 263, 274-75 (5th Cir. 2007) (citing *Sims v. Washex Machinery Corp.*, 932 S.W.2d 559, 562 (Tex. App.-Houston [1st Dist.] 1995, no writ)).

Texas law also applies the learned intermediary doctrine to medical products liability claims, which dictates that a manufacturer only has a duty to warn the prescribing physician of the product's dangers. *Porterfield*, 183 F.3d at 468 (citing *Bean v. Baxter Healthcare Corp.*, 865 S.W.2d 656, 663 (Tex. App.-Houston [14th Dist.] 1998, no writ)). However, a manufacturer may still be held liable for injuries sustained by the ultimate user if 1) the warning to the physician was defective; and 2) the failure to warn was a producing cause of the plaintiff's condition or injury. *Porterfield*, 183 F.3d at 468 (citing *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 911 (Tex. App.-El Paso 1989, writ denied)). "While the learned intermediary doctrine shifts the manufacturer's duty to warn from end user to intermediary, the plaintiff's burden of proof remains the same, i.e., to prove the product's warning was inadequate." *Gonzalez v. Bayer Healthcare Pharms., Inc.*, 930 F. Supp. 2d 808, 813 (S.D. Tex. 2013) (Harmon, J.) (citing *Centocor, Inc. v. Hamilton*, 372 S.W. 3d 140, 166 (Tex. 2012)).

To prevail under the learned intermediary doctrine, a plaintiff must "plead facts that would show her doctors were inadequately warned and but for those inadequacies her doctors would have recommended different treatment or given [her] counsel that would have led [her] to withhold consent." *Fearrington*, 410 F. Supp. 3d at 801 (citing *In re DePuy Orthopaedics, Inc.*, 888 F.3d 753, 775 (5th Cir. 2018)). A plaintiff's pleadings are insufficient when they do not identify the warning that her doctor received, allege how it was inadequate, demonstrate that a different warning would have changed the doctor's actions, or otherwise include facts necessary to allege the failure to warn caused her injury. *Gonzalez*, 930 F. Supp. 2d at 818. A complaint is impermissibly conclusory and vague where a plaintiff "only alleges generally that some of the problems with the [products] were made known to physicians [but] the magnitude, severity, and frequency of these problems were not disclosed[,] that Defendant knowingly provided incomplete and insufficient training and information

to physicians[, and] that [the plaintiff] would not have consented to use Defendant's [product] had Defendant given adequate warnings to Plaintiff and Plaintiff's implanting physicians." *Fearrington*, 410 F. Supp. 3d at 802.

Neither party disputes the applicability of the learned intermediary doctrine. Dkt. 16, 20. However, Boston Scientific contends Miles's complaint is factually deficient because it does not sufficiently allege "that if [Miles's] unnamed physician had known of a specific risk associated with the device that the physician would not have implanted the device into [her]" and "how any inadequacy in the warnings caused her alleged injuries." Dkt. 16 at 10. Miles maintains she is not required to name her physician and that her complaint pleads sufficient facts to allege a failure to warn claim. Dkt. 20 at 8-9.

Miles claims Boston Scientific "knowingly provided incomplete and insufficient training and information to physicians regarding the use of Advantage Fit" and failed to provide "sufficient or adequate warnings and instructions" regarding its dangers and adverse effects. Dkt. 1 at 10, 17. However, similar to the plaintiff's complaint in *Fearrington*, these statements are vague and conclusory as they do not identify the warning her doctor received or allege how it was inadequate. *See Gonzalez*, 930 F. Supp. 2d at 818. Miles's statement that "had Boston Scientific properly disclosed the risks associated with the [product], she would not have used it," is too vague to demonstrate how a different warning would have changed her physician's actions. Dkt. 1; *see also Gonzalez*, 930 F. Supp. 2d at 818. As such, the facts alleged in the complaint do not support a plausible claim that Boston Scientific inadequately warned Miles's physician and this failure was a producing cause of her injury.

C. Failure to State a Claim under Rule 9(b)

Lastly, Boston Scientific contends Miles's claims for fraud, fraud by concealment, and negligent misrepresentation are not pled with sufficient particularity as required by Federal Rule of Civil Procedure 9(b). Dkt. 16 at 12-15.

1. *Fraud and Fraud by Concealment*

Miles alleges Boston Scientific falsely represented that the Advantage Fit was safe and willfully and maliciously concealed facts regarding its safety from her and her physician. Dkt. 1 at 19-21. To prove a fraud claim under Texas law, a plaintiff must show that the defendant 1) made a material representation that was false; 2) knew the representation was false or made it recklessly as a positive assertion without any knowledge of its truth; 3) intended to induce plaintiff to act upon the representation; and 4) the plaintiff actually and justifiably relied upon the representation and thereby suffered injury. *Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001).

"The first requirement of this test can be met if the defendant concealed or failed to disclose a material fact when a duty to disclose existed." *United Teacher Assocs. Ins. Co. v. Union Labor Life Ins. Co.*, 414 F.3d 558, 566 (5th Cir. 2005); *see also Schlumberger Tech. Corp. v. Swanson*, 959 S.W.2d 171, 181 (Tex. 1997) (stating that "fraud by non-disclosure is simply a subcategory of fraud."). A duty to disclose exists: "1) where there is a special or fiduciary relationship; 2) where one voluntarily discloses partial information, but fails to disclose the entire truth; 3) where one makes a representation and fails to disclose new information that makes the earlier representation misleading or untrue; [or] 4) where one makes a partial disclosure and conveys a false impression." *In re Enron Corp. Sec.*, 388 F. Supp. 2d 780, 788 (S.D. Tex. 2005) (Harmon, J.).

Federal Rule of Civil Procedure 9(b) requires a party alleging fraud to state with particularity the circumstances constituting fraud. In applying this rule, the court has interpreted this to require a plaintiff to "specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Williams v. WMX Techs.*, 112 F.3d 175, 177 (5th Cir. 1997); *see also Benchmark Electronics, Inc. v. J.M. Huber Corp.*, 343 F.3d 719, 723 (5th Cir. 2003) (requiring allegations to include the time, place, and contents of the alleged false representations, as well as the identity of the person making the misrepresentation and what was fraudulently obtained to satisfy Rule 9(b)).

A plaintiff does not meet her burden when she alleges the willful deceit arises from a "sales and marketing [c]ampaign to promote the sale of the [products]," but does not provide details "as to any communications made pursuant to the alleged marketing campaign, from whom the communications originated except generally from the [d]efendant corporation, or when or where the communications were received by the alleged recipients." *Fearrington*, 410 F. Supp. 3d at 807. Allegations are too vague and conclusory when the plaintiff only "generally alleges that [d]efendant at some point misrepresented the [p]roducts as safe and effective." *Id.* A complaint alleging fraud also fails when it "does not identify the [defendant's] employee who came into [the] physician's office to make the representations on a specific day, or even point to a particular piece of the [product's] literature that contains a fraudulent representation." *Schouest v. Medtronic, Inc.*, 92 F. Supp. 3d 606, 611 (S.D. Tex. 2015) (Miller, J.).

Miles claims Boston Scientific promoted to physicians and patients "through various means and media" that the Advantage Fit was a "safe, effective, [and] reliable[] medical device" despite knowing it was not fit for its intended purpose and caused serious medical problems. Dkt. 1 at 6-7, 10. Alternatively, she claims Boston Scientific consistently underreported information about the

product's risks and knowingly provided "incomplete and insufficient training and information to physicians regarding the use of Advantage Fit and the aftercare of patients implanted with Advantage Fit." Dkt. 1 at 10.

Miles alleges the fraudulent acts or omissions stem from Boston Scientific's promotion and marketing of Advantage Fit, but this is too vague. *See Fearrington*, 410 F. Supp. 3d at 807. Miles's complaint provides no details regarding communications made as part of the marketing campaign or when or where the communications were received by the alleged recipients. *Id.* Further, Miles does not identify the speaker of those statements, only the general "Defendant." Dkt. 1 at 7. Therefore, Miles's complaint fails to comply with federal pleading standards for her fraud and fraud by concealment claims as she does not plead with specificity the time, place, or contents of the alleged false representations, or the identity of the person making the representation. *See Benchmark Electronics, Inc.*, 343 F.3d at 723; *Schouest*, 92 F. Supp. 3d at 611-12.

2. *Negligent Misrepresentation*

Claims for negligent misrepresentation also must be pled with particularity when they are based on the same set of facts as a plaintiff's fraud claim alleged in the complaint. *Benchmark Elecs.*, 343 F.3d at 723 (5th Cir. 2003); *see also Williams*, 112 F.3d at 177 (applying Rule 9(b) to state law claims of fraud and negligent misrepresentation when they rely on the same misrepresentations as alleged federal fraud claims set forth in a plaintiff's complaint). To prove a negligent misrepresentation claim, a plaintiff must show that "1) [a] representation is made by a defendant in the course of his business, or in a transaction in which he has a pecuniary interest; 2) the defendant supplies 'false information' for the guidance of others in their business; 3) the defendant did not exercise reasonable care or competence in obtaining or communicating the

information; and 4) the plaintiff suffers pecuniary loss by justifiably relying on the representation." *Gen. Elec. Capital Corp. v. Posey*, 415 F.3d 391, 395-96 (5th Cir. 2005).

Here, Miles's claim for negligent misrepresentation is based on the same facts as her fraud and fraud by concealment claims: Boston Scientific promoted to physicians and patients that the Advantage Fit was safe despite knowing it was not fit for its intended purposes and caused serious medical problems, Miles relied on these representations in submitting to implantation of the device, and as a result, she suffered injuries. Dkt. 1 at 7, 12. Therefore, Miles's claim for negligent misrepresentation must be pled with particularity as required by Federal Rule of Civil Procedure 9(b). *See Benchmark Elecs.*, 343 F.3d at 723.

Like her claims for fraud and fraud by concealment, Miles's negligent misrepresentation claim fails because it is not pled with particularity. Miles alleges Boston Scientific made false representations in its marketing and promotion of the Advantage Fit to physicians and patients. Dkt. 1 at 7. These facts are insufficiently pled as they lack details of the particular communications and do not identify the speaker of the representation, or when or where the particular communication was received. *See Fearrington*, 410 F. Supp. 3d at 807. As such, Miles's claim for negligent misrepresentation is not pled with particularity as she does not plead with specificity the time, place, or contents of the alleged false representations, or the identity of the person making the representation. *See Williams*, 112 F.3d at 177.

Lastly, Boston Scientific contends Miles's fraud-based and negligent misrepresentation claims must be dismissed because they are just another recitation of her flawed failure to warn claims. Dkt. 16 at 14-15. "When a patient alleges a fraud-by-omission claim against a prescription drug manufacturer for alleged omissions about a prescription drug's potential side effects, (1) the patient cannot plead around the basic requirements of a failure-to-warn claim, and (2) the learned

intermediary doctrine applies." *Centocor, Inc.*, 372 S.W. 3d at 169; *see also Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773 (S.D. Tex. 2008) (Tagle, J.) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims.").

Here, Miles's fraud by concealment and negligent misrepresentation claims are premised on her allegation that Boston Scientific knowingly omitted material facts about Advantage Fit's risks, or in other words, failed to adequately warn her and her physicians. Dkt. 1 at 10. Since the learned intermediary doctrine applies, her fraud-based and negligent misrepresentation claims fail for the same reasons as her failure to warn claim as discussed above. *See Ebel*, 536 F. Supp. 2d at 773.

IV. CONCLUSION

For the reasons stated above, Boston Scientific's motion to dismiss (Dkt. 15) is **GRANTED** in part and **DENIED** in part. Miles also seeks leave to amend her complaint in lieu of dismissal. Dkt. 20 at 11. The court also finds good cause to permit amendment, therefore Miles's request for leave to amend (Dkt. 20) is **GRANTED**. Miles must file her amended complaint within 14 days of the date of this order. If no amended complaint is filed, Miles's complaint will be **DISMISSED WITH PREJUDICE**.

Signed at Houston, Texas on July 9, 2020.

Gray H. Miller
Senior United States District Judge